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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,111

Applicant(s)

CLANCY ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 23-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 23-56 and 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1, 23-56 and new claims 57-59 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. ***Claim Objections Withdrawn:*** Claims 25-28 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend from only a single claim or multiple claims in the alternative and not multiple claims simultaneously; claims 25-28 depend from two claims simultaneously, is herein withdrawn in light of the amendment of claims 25-28 to only depend from a single claim and to recite additional methods steps.

1. ***Rejection Withdrawn:*** Claim 43-44 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. In light of the amendment of the claims to recite anti-gammaIFN antibodies and anti-IL-4 antibodies.

2. ***Rejection Withdrawn:*** Claims 51 and 52 rejected under 35 U.S.C. 112, second paragraph for depending from claim 48 which recites the phrase "IgG2 anti-H.pylori antibody- and/or gammaIFN- and/or IL-4-producing cells in the subject's blood" and reciting (Claim 51) "the frequency of IgG2 anti-H.pylori antibody-producing cells" and (Claim 52) "the frequency of gammaIFN-producing cells" has been obviated by amendment of claim 48 to provide antecedent basis for the phrases recited in claims 51-52.

Response to Arguments

3. Applicant's arguments filed September 16, 2005 have been fully considered but they are not persuasive.

1. ***Double Patenting Maintained:*** Claims 1, 23 and 24, 33-35 provisionally rejected under the judicially created doctrine of double patenting over claims 1, 10 and 15 of copending Application No. 10/332,112 is traversed on the grounds that the rejection will be addressed upon indication of allowable subject matter.

3. It is the position of the examiner that the copending species of 10/332,112 anticipates the instantly claimed genus; the provision obviousness type double patenting rejection is maintained for reasons of record. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

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4. **Rejection Maintained, 35 U.S.C. 112, second paragraph:** Claims 36-38 rejected under 35 U.S.C. 112, second paragraph recited the phrase “can be performed simultaneously with, a method which provides an indication of H.pylori status” is traversed on the grounds that claims 36-38 have been amended to stipulate that the status is gastrointestinal condition chosen from esophagus reflux, gastritis, dysplasia and gastric cancer. “Here, status refers to the gastrointestinal condition status of the subject whose antibody or cytokine level is determined” and assert the claims are now clear.

5. It is the position of the examiner that claims 36-38 recite the phrases “either simultaneously provides”, and “or can be performed simultaneously with, a method” and what is simultaneously carried out or provided is not clearly nor distinctly claimed.

The phrase “simultaneously provides” does not define a methods step or modification of an already recited methods step of the independent claim. This phrase does not positively define that anything is happening simultaneously with something else.

The examiner requested clarification as to what additional “method steps and reagents are used” simultaneously with the claimed methods of claims 1, 23 and 24 ?

6. The phrase “can be performed” is not a positively recited methods step. A future capability is not further limiting of a positively claimed methods step. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

While claims 36-38 have been amended to further define an indication of specific *Helicobacter* conditions, thus modifying the preamble of the claim or the recited intended use of the claimed method, how the methods of claims 36-38 are further limiting of claims 1, 23 and 24 by carrying out an additional “simultaneous” something is not distinctly claimed.

Claims 36-38 are still rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the reagents and or methods steps used together to produce an indication of *H.pylori* status. Does Applicant intend to further limit the type of sample being analyzed, ie the type of patient the sample is being taken from?

7. **Rejection Maintained Claim Rejections - 35 USC § 102 :** Claims 1, 29, 33, 36, 39, 42, 45 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Steer et al (1987) is traversed on the ground that Steer et al does not disclose the utilization of the instantly claimed control and asserts that some of the patients of Steer et al were not infected with *H.pylori*. Applicant asserts that the values in Table 3 are not average IgG2 values.

8. It is the position of the examiner that Steer et al measured IgG2 in gastritis patients, and ulcer patients. The level of IgG2 in the ulcer patient (1.8 ug/ml) relative to the infected control gastritis patient (5.8 ug/ml), was reduced. This is the method claimed. Steer et al carried out the claimed methods steps and determined the relative concentration of IgG2 to be reduced in an ulcer patient relative to a gastritis infected patient (see page 257, Table 3). The values

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determined and shown in Table 3, the mean of multiple values “Mean +/- SEM”, header on Table,3. The presence of the *Helicobacter pylori* pathogen was identified morphologically, and based upon catalase, oxidase reactions and rapid hydrolysis of urea (see page 255, first paragraph). The reference confirmed the presence of *H. pylori* infection in the patients along with antibody, IgG2 analysis.

9. With respect to new claim 57, it is the position of the examiner that while Steer et al does not mention the word cancer, the reference carried out the claimed methods steps with the same patient population, the same sample, the same control and compared the determined levels of IgG2 with the control (gastritis infected control). An indication of risk or the presence of gastric cancer is not a definite diagnosis of gastric cancer, therefore the claimed method which is defined by the claimed methods steps does not directly correlate with the recited intended use of the claimed method.

10. *Helicobacter pylori* infection was identified by Parsonnet et al (N. England Journal of Medicine, Vol. 325, pages 1127-1131) as a cancer risk factor cofactor in 1991. Steer et al confirmed the presence of *H. pylori* infection based upon determining IgG2 levels in an infected patient relative to an infected control population and found the determined level of IgG2 to be reduced; Steer et al still anticipates the instantly claimed methods.

11. The rejection is maintained for reasons of record. This rejection could be obviated by claiming a combination method of determining IgG2, IFN γ and IL-4.

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12. ***Rejection Maintained, Claim Rejections - 35 USC § 102:*** Claims 1, 29, 33, 36, 39, 42, 45, 48-49, 50-51 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Alison Rose Stacey (Dissertation, "Human Immune responses to Helicobacter pylori infection", July 1994), is traversed on the grounds that Stacey does not teach the claimed control which is an average of subjects infected with Helicobacter or subjects infected with Helicobacter that do not have gastric cancer.

13. It is the position of the examiner that Stacey does disclose the claimed invention, as well as the newly recited control. Stacey discloses that 45 sera from patients whose H.pylori status had been previously established by microbiological culture and Gram stain were evaluated for IgG2 levels (see page 81, Figure 3.4). H. pylori status is designated on the X axis and IgG2 the third and fourth columns. Patients infected with H.pylori which evidenced an IgG2 level below 9ug/ml control level (threshold average level) were determined (values below line) , as well as levels of IgG2 above the threshold average level were identified above the line.

At page 156 an average of the IgG2 antibody levels for treated and unsuccessfully treated patients are shown in Figure 7.1 a) and b). At page 157, paragraph 2, the median (average) IgG2 levels were determined as "good indicators of treatment success" using H.pylori specific IgG2 concentrations as an indicator. The patients averages were determined for H.pylori infected patients, specifically IgG2 Helicobacter pylori specific immunoreactivity prior to treatment (infected, control) and after treatment (reduced levels after treatment (see page 157, paragraph 2). The average values (median values) for unsuccessfully treated patients for H.pylori infection showed a slight reduction in IgG2 (see page 158, section 7.1.2 and Figure 7.1b) . The

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control value being the average value of IgG2 of all infected patients prior to treatment, as compared to the determined average value for IgG2 after unsuccessfully treating the patients.

At page 165, Stacey shows IgG2 antibody levels in patients still infected with *Helicobacter* after eradication therapy. Stacey in Section 7.1.2 states “The most pronounced reduction was with IgG2 antibodies where 52% of patients showed reduced levels of specific IgG2” after treatment but were patients were suffering from *H.pylori* infection due to unsuccessful treatment. The control level being pretreatment levels of 7.9 ug/ml (average value) (last paragraph page 158)) and the unsuccessful post treatment level being 6.0 ug/ml (average) wherein infection with *H.pylori* has been associated with forms of gastric cancer (line bridging pages 88-89; also see page 90, Chapter 4, first paragraph, discussion of progression toward gastric carcinoma (also see section 4.2, page 94; section 4.4, page 102, paragraph 3; pg 109, paragraph 1). Therefore, Stacey does disclose an average IgG2 control value from infected patients, determined the values of IgG2 in patient samples and compared the determined values post treatment with the infected control values to show the IgG2 values to be reduced relative to the control.

14. Applicant asserts that Stacey does not determine the frequency of the antibody producing cells in a patient subject sample, relative to an infected control.

15. Upon reconsideration of the definition of the term “frequency” provided by the instant Specification, the examiner found in Example 3, the steps of cellular staining (Stacey carried out intracellular nuclear staining (see page 67, section 2.13.2 “haematoxylin” (4 lines from bottom of page)), followed by identification of cytokine producing cells (Stacey utilized monoclonal antibodies to counter stain

antibody producing cells in the endoscopic biopsy samples for both T and B cells (see page 68, Table 2.3)). Stacey carried out the methods steps encompassed by the term “Frequency” functionally defined in Example 3 and broadly claimed.

Inherently Stacey discloses the instantly claimed method, in light of the fact that Stacey shows the determination of IgG2 antibody levels that are reduced in patients with chronic H.pylori infection (see Stacey chapter 7) and shows increased risk of cancer to be associated with H.pylori infection.

16. ***Maintained Claim Rejections - 35 USC § 102:*** The rejection of claims 48-50, 52, 54-55 and 58 under 35 U.S.C. 102(b) as being anticipated by Karttunen et al (1995) as evidenced by Deltenre et al (1995) is traversed on the grounds that :

- a. Karttunen et al “does not teach the determination of gammaIFN producing cells”;
- b. Karttunen et al “does not teach a control which represents about the average level of gammaIFN in subjected infected with Helicobacter.

17. It is the position of the examiner that Karttunen et al shows data from measuring gammaIFN secreting cells (see ledger narrative), relative to a control sample, the gammaIFN secreting cells having been previous stimulated by H.pylori antigen in vivo and the level of gammaIFN in the H.pylori gastritis is reduced relative to gastritis patients without H.pylori infection .

Additionally, Applicant’s traversal of Karttunen et al with respect to independent claim 48, and dependent claims by asserting the reference “does not teach a control which represents about the average level of gammaIFN in subjected infected with Helicobacter”, it is the position of the examiner that claim 48 and the dependent claims have not been amended to recite the

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combination of claim limitations utilized to traverse this prior art rejection; Applicant 's traversal is not commensurate in scope with the instantly claimed invention.

Karttunen et al still disclose the instantly claimed method as the references discloses the same or equivalent methods steps carried out by the instantly claimed method utilizing patient and control samples to assess gammaIFN associated with a human pathogen that causes chronic inflammation and produces diseases associated with stomach carcinoma due to long term consequences of H.pylori infection (see Karttunen et al, page 341, col. 1, bottom half of column).

18. ***Rejection Maintained Claim Rejections - 35 USC § 102:*** The rejection of claims 48-50, 53,54,55 and 59 under 35 U.S.C. 102(b) as being anticipated by Fan et al (1995) is traversed on the grounds that Fan et al do not determine the frequency of IL-4 producing cells and not the frequency of IL-4 producing cells.

19. It is the position of the examiner that Fan et al does disclose the instantly claimed method encompassing the step of determining the frequency of IL-4 producing cells. The frequency being staining (giemsa staining) followed by the cells being isolated/identified by cell type. Fan et al isolated lymphocytes (PBLs), and strained them to determine viability with acridine orange/ethidium bromide prior to co-incubation with H.pylori (see Table 3) and IL-4 levels were calculated relative to the frequency of viable, purified lymphocytes in the sample (Table 3).

20. Additionally, Fan et al isolated gastric tissue cells by biopsy, stained cells within the tissue biopsy sample with giemsa stain (page 289, col. 2, paragraph 2) and evaluated the biopsy tissue sample by histological examination (see page 290, col. 1, paragraph 3). The cells

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contained within the biopsy sample were identified and confirmed to contain cytokine producing cells based upon culturing of the cells (see Table 2, ledger narrative) followed by measuring cytokine production by EIA, (page 290, col. 1, paragraph 4). Fan et al still anticipates the instantly claimed invention.

21. ***Claim Rejections - 35 USC § 103 Maintained:*** The rejection of claim 56 under 35 U.S.C. 103(a) as being unpatentable over Fan et al (1995), as applied to claims 48-50, 53,54,55 above in view of Itoh et al (1999) is traversed on the grounds that Fan does not teach the determination of the frequency of IL-4 producing cells.

22. It is the position of the examiner that Fan et al does teach the determination of the frequency of IL-4 producing cells. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand allow the determination of the frequency of a cell type in a sample based upon staining and determining the presence of cytokine producing cells directly or indirectly. No specific structural properties are recited in the claims to define a specific method or species of determining the frequency of a specific cell type and therefore the claims are being read broadly to include the steps of staining and identifying cytokine producing cells by any known method or methods (direct labeling or indirect cytokine measurement). See discussion of Fan et al above. Fan et al in view of Itoh et al still obviate the instantly claimed invention.

New Claims/New Claim Amendments/New Grounds of Rejection

Claim Rejections - 35 USC § 112

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. 1, 23-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

25. Claims 1, and 23-47 recite the range “about the average” level. Original descriptive support for this range could not be found in the instant Specification. What the average is for the genus of *Helicobacter* infected subjects recited in the claims is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the Specification defines three types of controls at page 6, lines 7-13, the claim amendment does not set forth any of the specific embodiments defined at page 6. Additionally, the range encompassed by the phrase “about the average” does not evidence original descriptive support in the instant Specification and is New Matter. Claims 1 and 23-47 recite New Matter for the reasons set forth above.

26. Claims 1 and 23-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All of the claims have been amended to recite the phrase “about the average level of”.... “in subjects infected with *Helicobacter*” in reference to a predetermined control for the recited analysis. The claims now recite a genus of controls that comprise average levels obtained from any infected subject, the controls being for the selected analyte, IgG2, gammaIFN or IL-4.

While the Specification describes controls with uncomplicated chronic gastritis or asymptomatic infection by *H.pylori* as serving as reference control levels (see page 6, lines 7-12) in a method of determining risk (IgG2 or IL-4) of or the presence of cancer (IgG2, IL-4 and IFN-gamma), the Specification has not described how any control value from any *Helicobacter pylori* infected subject could serve as a reference control in the claimed method.

The instant Specification defines subjects infected with *Helicobacter* to include subjects with chronic gastritis, duodenal ulcer, gastric ulcer, gastric cancer, esophagus reflux (figures 1-5), non-ulcer dyspepsia, metaplasia and dysplasia (instant Specification, page 1, lines 11-15). The control predetermined level may be obtained from any or all of these patients based upon the broad recitation of the first control recited in the claims, or from all infected patients but the gastric cancer patients in the second control recited in the claims.

27. The examiner upon consideration of Figure 4 found levels of IgG2 obtained from patients with esophagus reflux, chronic gastritis, gastric cancer and dysplasia/eradicated. In light of the first control using the IgG2 values from gastric cancer infected patients as the predetermined control, a determined level of IgG2 in a subject with reduced levels of IgG2 lower than the

average of IgG2 in an *Helicobacter* infected patient with gastric cancer would result in a false positive, in light of the fact that patients that are designated dysplasia/eradicated still evidence lower levels of IgG2 than the predetermined first control but are no longer at risk of cancer associated with *Helicobacter* infection as *Helicobacter pylori* infection was eradicated.

Upon consideration of Figure 1 with respect to gammaIFN values, the figure shows the average value of gammaIFN in gastritis patients to be is higher than that found in patients with carcinoma, but lower than patients with dysplasia. Utilizing the gastritis value as the predetermined control value and comparing this value with a value obtained from a patient infected with *Helicobacter* evidencing dysplasia (based upon the gammaIFN values shown) the dysplasia patient would be determined not to be at risk of cancer as the value of gammaIFN for the dysplasia patient *is not reduced* relative to the gastritis control, but the instant Specification states that dysplasia is a precancer lesion associated with increased risk of cancer (see page 2, lines 18-20). A gastritis control level of IFN-gamma would not serve to determine risk in a patient with dysplasia when the subject value of IFN-gamma is elevated in dysplasia patients, dysplasia being an indicator of risk of gastric cancer. A gastritis *Helicobacter* infected control value for gamma IFN would be a predetermined control for gastric cancer (Figures 1 and 3) and not a control value for indicating a dysplasia patient is at risk because dysplasia patients produce higher levels of IFN-gamma than those of a gastritis patient.

In light of the discussion with respect to the species of controls described and disclosed that will effectively work in the instantly claimed methods, the instant Specification has not described the claimed genus of controls that may comprise values obtained from any and all *Helicobacter* infected subjects as a reference control value (predetermined control) in a method

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of determining risk or the presence of gastric cancer. Therefore, the instant Specification has not described the genus of claimed controls obtained from any *Helicobacter* infected patient in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that the written description provision of 35 USC 112 is serviceable from its enablement provision.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US005567594A (see claim 5), US 20050169901A1, US 20040126356A1, US 20040038329A1, EP000439462B1 and WO98/48836 are cited to show methods of detecting or evaluating *Helicobacter pylori* antibodies/immunoglobulins and cytokines.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp

November 17, 2005


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